UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trad mark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/189,702	11/10/98	LETTE A	18623-013410

HM11/0720

ELLEN LAUVER WEBER
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER	
SCHWADRON, R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/189,702	Sette et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 4/9/2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 2-22 is/are pending in the application.

4a) Of the above, claim(s) 2-6, 12-15, 18-22 is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 7-11, 16, 17 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

1. Applicant's election of the species peptide attached to a T helper epitope in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 18-22 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected species. Election was made **without** traverse in Paper No. 15. Claims 2-6,12-15 were previously withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions or species as per paragraphs 1 and 2 of the previous Office Action.

3. Claims 7-11,16,17 are under consideration.

4. The abstract of the disclosure is objected to because it does not disclose the currently claimed invention (eg. p53 peptides which bind HLA A2.1). Correction is required. See MPEP § 608.01(b).

5. As per the first line of the specification and the filed declaration, the instant application only claims priority to 08/205713. The term "related" is not recognized as a claim to priority to a particular application.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7-11,16,17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the peptides recited in claim 7 wherein the recited peptides are "immunogenic". Sherman et al. teach that in order to establish that a peptide is immunogenic, that it is necessary to establish that a peptide binds an MHC molecule and can give rise to a CTL response (see page 50, lines 13,14). The specification provides no evidence that the peptides recited in claim 7 can give rise to a CTL response. Sherman et al. also teach that not all peptides which bind HLA class I give rise to CTL (eg. not all HLA binding peptides are immunogenic, see page 95, second from last paragraph). Therefore, the specification is not enabling for the claimed invention.

8. It appears that the peptide of SEQ. ID. NO. 4 (SMPPPGTRV) is free of the prior art. The search of the prior art has been extended to the peptide of SEQ. ID. NO. 15 (CQLAKTCPV). Claim 10 has only been searched with regards to the peptide of SEQ. ID. NO. 4 (eg. the other peptides recited in said claims have not been searched). Regarding priority for the claimed invention, the claimed inventions are not disclosed in parent application 08205713, and therefore the priority date for the claimed inventions with regards to the application of prior art is that of the instant application. It is noted that the priority date for an individual claim is based on the elements recited in the claim. For example, a claim that recites 50 peptides disclosed in a parent application and one peptide not disclosed in said parent application is not entitled to priority to the parent application with regards to the application of prior art (see MPEP section 706.02, page 700-10, Rev. 1, Feb 2000).

9. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 appears to state that the immunogenic peptide is less than about 15 amino acids in length. However, claim 17 then states that the peptide is linked to a helper cell epitope. This epitope would be approximately 13-25 amino acids long. Therefore, the immunogenic peptide containing a helper and CTL epitope would now be at least 21-33 amino acids long (if the CTL epitope was only 8 amino acids). Such a peptide is longer than about 15 amino acids and therefore said peptide lacks antecedent basis in claim 7.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 7-9,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuebler et al. (WO 96/22067).

Kuebler et al. teach a peptide which encompasses the peptide of claim 7 wherein said peptide is less than 15 amino acids and comprises SEQ. ID. No. 15 (see FCQLAKTCPV), Figure 14, wherein said peptide is a known CTL epitope (see page 9, third paragraph). Kuebler et al. also teach "ratchet libraries" that would contain the peptide CQLAKTCPV (eg. see pages 31 and 32, and Figure 14, and claims 1, 8 and 9). Kuebler et al. teach said peptides in a pharmaceutically acceptable carrier (see page 19, first two sentences).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 7-9,16,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuebler et al. (WO 96/22067) in view of Grey et al. (WO 94/20127).

Kuebler et al. teach a peptide which encompasses the peptide of claim 7 wherein said peptide is less than 15 amino acids and comprises SEQ. ID. No. 15 (see FCQLAKTCPV), Figure 14, wherein said peptide is a known CTL epitope (see page 9, third paragraph). Kuebler et al. also teach "ratchet libraries" that would contain the peptide CQLAKTCPV (eg. see pages 31 and 32, and Figure 14, and claims 1, 8 and 9). Kuebler et al. teach said peptides in a pharmaceutically acceptable carrier (see page 19, first two sentences). Kuebler et al. do not specifically teach said peptides conjugated to a helper cell epitope. Grey et al. teach that CTL stimulating peptides can linked to T helper epitopes for the purpose of increasing the immunogenicity of said CTL peptide (see page 18, penultimate paragraph). It would have been prima facie obvious to one of ordianry skill in the art at the time the invention was made to have created the claimed invention because

Kuebler et al. teach the claimed invention except for a linked T helper epitope and Grey et al. teach that CTL stimulating peptides can linked to T helper epitopes for the purpose of increasing the immunogenicity of said CTL peptide. One of ordinary skill in the art would have been motivated to do the aforementioned because Grey et al. teach that CTL stimulating peptides can linked to T helper epitopes for the purpose of increasing the immunogenicity of said CTL peptide.

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
June 27, 2001